

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/819,667	03/29/2001	Tetsuya Yano	35.C15229	3225	
5514	7590 05/15/2002				
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EXAMINER		
			GOLDBERG, JEANINE ANNE		
			ART UNIT	PAPER NUMBER	
			1634	11	
			DATE MAILED: 05/15/2002	(/ -	

Please find below and/or attached an Office communication concerning this application or proceeding.

'								
	Application	No.		Applicant(s)				
	09/819,667			YANO ET AL.				
Office Action Summary	Examiner			Art Unit				
	Jeanine A C			1634				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
1) Responsive to communication(s) filed on $\underline{2}$								
2a) ☐ This action is FINAL . 2b) ☐	This action is n	on-fina	al.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims								
4) Claim(s) 1-25 is/are pending in the applicat	ion.							
4a) Of the above claim(s) <u>19-25</u> is/are withdo		iderati	ion.					
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>1-18</u> is/are rejected.								
7)☐ Claim(s) is/are objected to.								
8) Claim(s) are subject to restriction and	d/or election re	quirem	ent.					
Application Papers								
9) The specification is objected to by the Examiner.								
10)☐ The drawing(s) filed on is/are: a)☐ ad								
Applicant may not request that any objection to								
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12) The oath or declaration is objected to by the	Examiner.							
Priority under 35 U.S.C. §§ 119 and 120								
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a)⊠ All b)⊡ Some * c)⊡ None of:								
1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.								
Attachment(s)								
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No()	5) 🔲 1		ary (PTO-413) Pape Il Patent Application				

Art Unit: 1634

DETAILED ACTION

Priority

1. This application claims priority to a foreign filed document published in Japanese, filed March 30, 2000.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - 1. Claims 1-18, drawn to nucleic acids, classified in class 536, subclass 23.1.
 - II. Claims 19-25, drawn to methods of detecting a PHA synthesizing microorganism using the nucleic acids of Group I, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I are generic and may be used in any method such as aptamer methods, purification methods, hybridization assays, and antisense methods. The nucleic acids of Group I

Art Unit: 1634

Page 3

are very broadly drawn to fragments of SEQ ID NO: 1-9 and fragments embedded within larger sequences. Therefore, the claims essentially read upon any nucleic acids known in the art.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.
- 4. During a telephone conversation with Peter Saxon on April 26, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18.

 Affirmation of this election must be made by applicant in replying to this Office action.

 Claims 19-24 are withdrawn from further consideration by the examiner, 37

 CFR 1.142(b), as being drawn to a non-elected invention. Applicant requested that upon indication of allowability for Group I, Group II be rejoined.
- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1634

Sequence Rules

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

It is noted that on page 56, line 11, and page 54, line 2 of the specification, for example, contains nucleotide sequences longer than 10 nucleotides. The nucleotide sequences have not been identified by SEQ ID NO:. Appropriate correction is required.

Claim Objections

7. Claims 2-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

It is unclear from Claim 1 what is required, however, in the event that applicant intended to claim a nucleic acid consisting of SEQ ID NO: 1-9, Claims 2-18 fail to further limit the claim because the claims allow modifications of the nucleic acid such that the nucleic acid is fragments, mutations, partial sequences. It appears from Claim 3, that Claim 1 may have been intended to allow for complementary base sequences of the modified sequence, however, as written the claim does not appear to encompass such an embodiment. The clause "or complementary base sequence thereof" appear to be

Art Unit: 1634

modifying the immediately preceding clause and not the clause following the recitation "or complementary base sequence thereof".

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 8. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) Claims 1-18 are indefinite over the recitation, in Claim 1, "a nucleic acid fragment selected from any of a base sequence show in SEQ ID NO: 1-9" because it is unclear whether the claim is directed to smaller fragments from SEQ ID NO: 1-9 or is directed to a fragment comprising SEQ ID NO: 1-9. Moreover it is unclear whether the claim is directed to open or closed claim language in the event that applicant intended to claim to be the former. In the event that applicant intended the claim to read upon a fragment of SEQ ID NO: 1-9, namely nucleotide A, embedded within a larger sequence the claim would encompass nearly every nucleic acid. With respect to "modified sequence subjected to a mutation based upon these base sequence", it is unclear what the metes and bounds of the nucleic acid encompass. It is unclear whether the claim is directed to a nucleic acid which contains the nucleotides of SEQ ID NO: 1 in any order, modified, or whether the claim is directed to a nucleic acid which is modified by a

Art Unit: 1634

Page 6

mutation to encompass a deletion of all but one nucleotide. In essence, it is unclear what the claimed nucleic acid requires and the structure has not been provided.

- B) Claim 2-18 is indefinite over the recitation "comprising the nucleic acid fragment according to Claim 1, or a nucleic acid fragment comprising a partial sequence in a base sequence thereof". The claim appears to be broadening the scope of the invention since the claim allows for nucleic acids comprising the fragment of SEQ ID NO: 1-9 or a modified sequence which was not claimed in Claim 1.
- C) Claims 3-4 are indefinite because it appears to be broadening the base claim. It appears from Claim 3, that Claim 1 may have been intended to allow for complementary base sequences of the modified sequence, however, as written the claim does not appear to encompass such an embodiment. The clause "or complementary base sequence thereof" appear to be modifying the immediately preceding clause and not the clause following the recitation "or complementary base sequence thereof". The claim is further directed to an embodiment "substitution of bases in the base sequence with other base or base sequence". It is unclear whether this is intended to mean a completely different not related nucleic acid sequence such that all of the bases in the base sequence of SEQ ID NO: 1-9 have been substituted with other base sequences. Clarification is requested. Claim 4 has a similar recitation and therefore is similarly unclear.
- D) Claims 5-18 are further directed to nucleic acid molecules however the molecules appear to contain additional matter. The claim includes a recitation "a moiety capable of binding to a solid-phase carrier may be introduced". It is unclear whether the

Art Unit: 1634

claim requires a moiety is required to be attached to the nucleic acid or whether the claim is directed to a nucleic acid which may have such a modification. It is noted, reading the claim in the broadest reasonable interpretation, the claim encompasses a "marker/moiety" to encompass nucleotides. Nucleotides may be used as markers and nucleotides may further be used as able to bind to a solid phase carrier.

- E) Claim 7 is indefinite because it is unclear whether the primer contains a combination of two kinds of nucleic acid fragments or whether the claim was intended to be directed to two different nucleic acid fragments. The specification does not teach what different kinds of nucleic acid fragments encompass. It is unclear what kinds of nucleic acid fragments are encompassed by the instant claims. Further, as written the claim appears to be directed to a single primer containing two kinds of nucleic acid fragments. It is unclear how a single nucleic acid may contain two kinds of nucleic acid fragments. Moreover, the claim requires that these two kinds of nucleic acid fragments are substantially different in base sequence. It is unclear how the fragments are substantially different in base sequence, i.e. whether they are different nucleotides, whether they are different analogs or some other difference. Furthermore, it is unclear whether the primer comprises two kinds of nucleic acid fragments and a marker and/or moiety based upon the confusing claim language. Thus the metes and bounds of the claimed invention are indefinite.
- F) Claims 10-13 are indefinite over the recitation "solid-phase carrier into a 5'-terminal side" because it is unclear what "into a 5'-terminal side" is intended to mean. Furthermore, Claims 10-13 are indefinite over the recitation of "capable of binding to a

Art Unit: 1634

solid-phase carrier" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited probes/primers have the potential to bind to a solid-phase carrier or do in fact bind to a solid-phase carrier. Amendment of the claim to read, for example, "nucleic acid comprises a marker or moiety which binds to a solid-phase carrier wherein the marker or moiety is attached to the 5'-terminus of the nucleic acid" would obviate this rejection.

G) Claims 14-18 are indefinite over the recitation of "capable of binding to a solid-phase carrier" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited probes/primers have the potential to bind to a solid-phase carrier or do in fact bind to a solid-phase carrier. Moreover, Claims 14-18 appear to be Markush like claims. As provided in MPEP 2173.05(h), "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925)."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1634

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 9. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Engel et al (US Pat. 6,287,779, Sept 11, 2001).

Engel teaches primer sequences for various organisms (Table 2).

Engel teaches the elements of Claim 1 directed to a nucleic acid fragment from SEQ ID NO: 1-9 which is modified subjected to a mutation based upon the sequence. Specifically Engel teaches a nucleic acid (SEQ ID NO: 18) in which the first nucleotides TTTGCC and the terminating nucleotides cactgtgaaca have been modified or deleted, thereby leaving a fragment of SEQ ID NO: 1, namely aaaac.

With respect to Claim 2, Engel, as explained above teaches a fragment comprising a partial sequence of SEQ ID NO: 1, namely agaac.

With respect to Claim 3 and 4, Engel teaches a nucleic acid fragment of SEQ ID NO: 1, for example, which deletes and then modifies the deleted regions to obtain SEQ ID NO: 18 provided in Table 2.

With respect to Claims 5-6, 8, 10-11, 13 Engel teaches the primers may be detectably labeled (col 6, lines 24-25). Moreover, Engel also teaches aaaac, a fragment of SEQ ID NO: 1 of the instant application attached to 6 nucleotides on the 5' end which may be a marker for capture on a solid support.

Art Unit: 1634

With respect to Claims 7, 9, 12, SEQ ID NO: 18 of Engel contains at least two kinds of nucleic acid fragments with substantial difference in base sequence. For example, Engle teaches a primer, SEQ ID NO: 18, with a fragment of three "T's" attached to a fragment of "G" attached to a fragment of 2 "C's" attached to a fragment of 4 "A's"....etc.

10. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Pat. 5,474,796, December 12, 1995).

Brennan teaches an array containing oligonucleotides having 10 nucleotides each (10-mers). The array represents every possible permutation of the 10-mer oligonucleotide (col 9, lines 55-60).

Brennan teaches the elements of Claim 1 directed to a nucleic acid fragment from SEQ ID NO: 1-9. Since Brennan teaches every 10-mer nucleic acid, each fragment from SEQ ID NO: 1-9 of 10 nucleotides in length is anticipated. Moreover, for example, Brennan teaches a nucleic acid of gcctckgaaa, a fragment from SEQ ID NO: 1. With respect to Claim 2, Brennan, as explained above teaches a nucleic acid fragment comprising a fragment of each of SEQ ID NO: 1-9. Moreover, Brennan teaches nucleic acids which are modifications of SEQ ID NO: 1-9 such that part of the sequences were deleted, or substituted. Moreover, the nucleic acids contain nucleotides which are capable of being detected and binding to a solid support at the 5' terminal.

Art Unit: 1634

11. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Huisman et al. (J. of Biol. Chem. Vol 266, pages 2191-2198, 1991).

To the extent that the Claims read on a nucleic acid comprising SEQ ID NO: 1-9, the following rejection would be appropriate. The claims do not require any specific length limitation, therefore, the entire PHA gene could be used as a probe for detection of the gene itself. Each of Claims 2-14 specifically allow for additional sequences on the ends of SEQ ID NO: 1-9.

Huisman et al. (herein referred to as Husiman) teaches the nucleotide sequence of the gene which encodes PHA biosynthetic enzymes from *P. oleovorans* (see Figure 2, pages 2194). SEQ ID NO: 1-9 are each embedded within the nucleotide sequence depicted in Figure 2. SEQ ID NO: 1, nucleotides 590-612 of Figure 2; SEQ ID NO: 2, nucleotides 936-958 of Figure 2; SEQ ID NO: 3, nucleotides 1265-1288 of Figure 2; SEQ ID NO: 4, nucleotides 1490-1516 of Figure 2; SEQ ID NO: 5, nucleotides 2089-2113 of Figure 2; SEQ ID NO: 6, nucleotides 3548-3572 of Figure 2; SEQ ID NO: 7, nucleotides 3787-4012 of Figure 2; SEQ ID NO: 8, nucleotides 4507-4530 of Figure 2; and SEQ ID NO: 9, nucleotides 1977-2001 of Figure 2. Therefore, Huisman teaches every limitation of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1634

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 13. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huisman et al. (J. of Biol. Chem. Vol 266, pages 2191-2198, 1991) in view of Solainman et al. (Appl. Microbiol. Biotechnol. Vol 53, pages 690-694, June 2000) and Dieffenbach et al. (PCR Methods and Applications, Vol 3, No. 3, pages S30-37, 1993).

To the extent that the Claims read on a nucleic acid consisting of SEQ ID NO: 1-9, the following rejection would be appropriate.

Huisman et al. (herein referred to as Husiman) teaches the nucleotide sequence of the gene which encodes PHA biosynthetic enzymes from *P. oleovorans* (see Figure 2, pages 2194). SEQ ID NO: 1-9 are each embedded within the nucleotide sequence depicted in Figure 2. SEQ ID NO: 1, nucleotides 590-612 of Figure 2; SEQ ID NO: 2,

Art Unit: 1634

nucleotides 936-958 of Figure 2; SEQ ID NO: 3, nucleotides 1265-1288 of Figure 2; SEQ ID NO: 4, nucleotides 1490-1516 of Figure 2; SEQ ID NO: 5, nucleotides 2089-2113 of Figure 2; SEQ ID NO: 6, nucleotides 3548-3572 of Figure 2; SEQ ID NO: 7, nucleotides 3787-4012 of Figure 2; SEQ ID NO: 8, nucleotides 4507-4530 of Figure 2; and SEQ ID NO: 9, nucleotides 1977-2001 of Figure 2.

Huisman does not teach nucleic acids consisting of SEQ ID NO: 1-9.

However, Solaiman et al. (herein referred to as Solaiman) specifically teaches using PCR protocol for specific detection of genes coding for polyhydroxyalkanoate (PHA) synthesis using primers. Solaiman teaches that "either purified genomic DNA or lysate of colony suspension can serve equally well as the target sample for the PCR, thus affording a simple and rapid screening of phaC1/C2-containing microorganisms" (abstract). Solaiman teaches a forward primer, I-179L, which is position 3936-3963 of the nucleotide sequences of Huisman. Solaiman teaches that the primers were based upon two highly conserved sequenced deduced from a multiple alignment analysis of pseudomonad phaC genes (page 691, col 1).

Moreover, Dieffenbach et al. (herein referred to as Dieffenbach) teaches general concepts for PCR primer design. The guidelines are generally directed to size of the oligonucleotide, base pair composition, GC content, and teaches that numerous computer software programs design primers based upon algorithms.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the teachings in the art which teach the full length nucleic acid sequence of the phaC gene, Huisman, with the teachings of specific primers from the

Art Unit: 1634

phaC gene, Solaiman, and the general teaching of how to design appropriate primers, Dieffenbach. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologues, however, the court stated

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Since the claimed oligonucleotides simply represent functional equivalents of the disclosed primer sequence taught by Solaiman concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited reference in the absence of secondary considerations. Given the high level of skill in the art at the time the invention was made, the ordinary artisan would have been motivated to have designed alternative primers based upon the guidance provided by Dieffenbach and the entire gene sequence taught by Huisman. Designing primers was routine in the art and the ordinary artisan would have been motivated to have designed additional primers for amplification and detection of the phaC genes.

Art Unit: 1634

14. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huisman et al. (J. of Biol. Chem. Vol 266, pages 2191-2198, 1991) in view of Doi et al (US Pat. 5,968,805, October 1999).

To the extent that the Claims read on a nucleic acid consisting of SEQ ID NO: 1-9, the following rejection would be appropriate.

Huisman et al. (herein referred to as Husiman) teaches the nucleotide sequence of the gene which encodes PHA biosynthetic enzymes from *P. oleovorans* (see Figure 2, pages 2194). SEQ ID NO: 1-9 are each embedded within the nucleotide sequence depicted in Figure 2. SEQ ID NO: 1, nucleotides 590-612 of Figure 2; SEQ ID NO: 2, nucleotides 936-958 of Figure 2; SEQ ID NO: 3, nucleotides 1265-1288 of Figure 2; SEQ ID NO: 4, nucleotides 1490-1516 of Figure 2; SEQ ID NO: 5, nucleotides 2089-2113 of Figure 2; SEQ ID NO: 6, nucleotides 3548-3572 of Figure 2; SEQ ID NO: 7, nucleotides 3787-4012 of Figure 2; SEQ ID NO: 8, nucleotides 4507-4530 of Figure 2; and SEQ ID NO: 9, nucleotides 1977-2001 of Figure 2.

Huisman does not teach nucleic acids consisting of SEQ ID NO: 1-9.

However, Doi et al. (herein referred to as Doi) teaches using an oligonucleotide consisting of 5' CC(G/C)CAGATCAACAAGTT(C/T)TA(C/G)GAC-3' as a probe for obtaining a DNA fragment. Doi teaches that the oligonucleotide is from a well-conserved region. The oligonucleotide was labeled with digoxigenin using DIG DNA labeling kit (col 5, lines 5-15). The nucleic acid oligonucleotide probe is located at positions 1220-1244 of the nucleic acid of Huisman.

Art Unit: 1634

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the teachings in the art which teach the full length nucleic acid sequence of the phaC gene, Huisman, with the teachings of specific probe from the phaC gene, Doi. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologues, however, the court stated

"Normally, a prima facie case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Since the claimed oligonucleotides simply represent functional equivalents of the disclosed probe sequence taught by Doi concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited reference in the absence of secondary considerations. Given the high level of skill in the art at the time the invention was made, the ordinary artisan would have been motivated to have designed alternative probes based upon the entire gene sequence taught by Huisman. Designing probes was routine in the art and the ordinary artisan would have been motivated to have designed additional probes/primers for amplification and detection of the phaC genes.

Art Unit: 1634

Conclusion

15. No claims allowable over the art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg Holdburg May 8, 2002

> Supervisory Patent Examiner Technology Center 1600